



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 16 1998

6266 '98 SEP 21 P1:51

Mr. David Hilton
Vice President
Samra Health & Beauty, Inc.
3000 S. Robertson Boulevard
Suite 420
Los Angeles, California 90034

Dear Mr. Hilton:

This is in response to your letter of September 8, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Samra Health & Beauty, Inc. is making the following claim, among others, for the product "Samra Immune Booster:" "...protect the body from pathogens."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to mitigate, treat, cure, or prevent disease, namely infections or diseases caused by pathogenic microorganisms. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

975-0163

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Page 2 - Mr. David Hilton

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#61170)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:9/15/98:docname:61170.adv:disc32

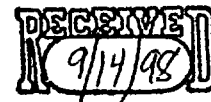
The logo for Samra Health & Beauty, Inc. features the word "Samra" in a stylized, cursive script. To the right of the word is a circular emblem containing a traditional Chinese landscape painting with mountains, water, and a small boat.

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61170

September 8, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington DC 20204



Dear Sirs:

This notice is to inform you that the following company:

Samra Health & Beauty, Inc.
3000 S. Robertson Blvd., Suite 420
Los Angeles, CA 90034

will be making the following statements in the labeling of dietary supplements:

1. Product: Samra Anti Aging

Statement: "Traditional Chinese Medicine (TCM) believes that a long and healthy life is the result of good nutrition, a healthy lifestyle and an active mind and body. Samra's Anti-Aging provides an exclusive combination of precious herbs together with essential vitamins and minerals to promote optimal health and vitality."

2. Product: Samra Balanced Woman

Statement: "Traditional Chinese Medicine (TCM) believes that to promote optimal health, a woman's circulatory and hormonal systems must be in balance. Young women must have healthy bone and liver functions to produce and store blood. As women age, healthy kidneys play an important role in the production of essential hormones. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

3. Product: Samra Brain Power

Statement: "Traditional Chinese Medicine (TCM) believes that to stimulate the brain it is necessary to bring into balance the complimentary elements in the body that effect the brain. The heart must function optimally to send blood to the brain. The lungs must be strong and clean to oxygenate the blood. The liver and kidneys must be in a state of balance to cleanse the blood. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

4. **Product: Samra Children's Vita-Herb**

Statement: "Traditional Chinese Medicine (TCM) believes that a growing child needs the right balance of nutrition, a healthy lifestyle, and an active mind and body for proper growth and development. The Children's Vita-Herb by Samra provides an exclusive combination of herbs together with sixteen essential vitamins and minerals to promote optimal health, growth and energy.

5. **Product: Samra Detoxify**

Statement: "Traditional Chinese Medicine (TCM) believes that to achieve a long and healthy life the body must be able to dispel harmful toxins. The liver and kidneys, as the chief purifiers of the blood must be strong and healthy. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

6. **Product: Samra Digest Ease**

Statement "Traditional Chinese Medicine (TCM) believes that to promote proper digestion and efficient absorption of nutrients the body's systems must be in balance. The stomach, liver, intestines and spleen must function in harmony to transform and transport essential nutrients throughout the body. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

7. **Product: Samra Healthy Hair**

Statement: "Traditional Chinese Medicine (TCM) believes that to promote healthy hair, the scalp must receive the proper nutrients. A balance of strong circulation and healthy blood is essential to nourish the scalp and hair. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

8. **Product: Samra Healthy Prostate**

Statement: "Traditional Chinese Medicine (TCM) believes that as the body ages, toxins may begin to accumulate in the liver and kidneys diminishing their ability to cleanse and nourish the blood. As a result of this, other body organs and glands (such as the prostate) absorb damaging toxins which can effect their natural functions. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

9. **Product: Samra Immune Booster**

Statement: "Traditional Chinese Medicine (TCM) believes that a strong immune system is supported by many elements. The lungs are the first line of defense, they expel toxins, phlegm, and protect the body from pathogens. Next the blood and spleen support the body's immune capability. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

10. **Product: Samra Potent Man**

Statement: "Traditional Chinese Medicine (TCM) believes that a healthy and virile life requires inner balance and mental well-being. Healthy kidneys are needed to balance hormones, a healthy spleen provides nutrients and energy to the body. Finally, a calm mind frees the soul. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

samra health & beauty, inc.

11. **Product: Samra Stress Relief**

Statement: "Traditional Chinese Medicine (TCM) believes that a healthy and happy life requires a balance between the mind and body. Mental well being results from a rested mind and a calm spirit. The body system must be refreshed with renewed energy from natural nutrients and healthy blood to defend against mental stress. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

12. **Product: Samra Ultra Circulation**

Statement: "Traditional Chinese Medicine (TCM) believes that to promote a healthy circulatory system requires a healthy heart, flexible blood vessels, healthy blood cells, and efficient lungs to oxygenate the blood. The kidney and liver must also be in balance to store blood. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

13. **Product: Samra Ultra Energy**

Statement: "Traditional Chinese Medicine (TCM) believes "vital energy" is the result of the harmonious balance of the life force (Qi) within us. Energy results from different sources within the body: the lungs to oxygenate blood, the spleen to transmit nutrients to the body, and a clear mind to promote quick reflexes. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."


14. **Product: Samra Vita Herb**

Statement: "Traditional Chinese Medicine (TCM) believes that a healthy life is the result of good nutrition, a healthy lifestyle, and an active mind and body. Samra's Vita Herb provides an exclusive combination of principle herbs together with essential vitamins and minerals to promote optimal health, well-being and energy."

15. **Product: Samra Weight Loss**

Statement: "Traditional Chinese Medicine (TCM) believes that excess weight can be the result of imbalances within the body. Digestive stagnation, water retention, an imbalance in metabolism or even physical or mental stress can all contribute to excess weight. TCM herbal formulas are designed to promote optimal health by establishing the body's natural balance."

The information contained herein is complete and accurate. Samra Health & Beauty, Inc. has competent and reliable substantiation that the above statements are truthful and not misleading.



David Hilton
Vice President
Samra Health & Beauty, Inc.